

REMARKS

I. Status Summary

Claims 1-18 were filed with the subject application and have been examined by the U.S. Patent and Trademark Office (hereinafter "the Patent Office"). Of these, claims 1-9 and 15-18 have been withdrawn in response to the March 13, 2006 Restriction Requirement. Accordingly, claims 10-15 are currently pending in the subject application.

The Patent Office has objected to the Information Disclosure Statements (IDS) submitted December 8, 2003 and November 21, 2005, as allegedly not being submitted in the proper format, *i.e.*, on form PTO-892.

The Patent Office has objected the drawings, as Figure 4 allegedly does not correspond to the brief description of Figure 4 listed in the specification.

Claims 10-12 presently stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by PCT International Patent Application No. WO 99/45018 to Hicklin *et al.* (hereinafter referred to as "Hicklin *et al.*").

Claims 10-15 presently stand rejected under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent Application No. 5,853,719 to Nair *et al.* (hereinafter referred to as "Nair *et al.*") as evidenced by Heer *et al.* (2001) *Clin Can Res* 7:3491-3494 (hereinafter referred to as "Heer *et al.*").

Claims 10 and 12-15 have been amended herein. Support for the amendments can be found throughout the specification as filed, including particularly at paragraph [0020], page 5; paragraph [022], page 6; and paragraph [0059], page 13. No new matter has been added.

New claims 19-35 have been added. Support for new claims 19-35 can be found throughout the specification as filed, including particularly at paragraph [0018], page 5; paragraph [0019], page 5; paragraph [0022], page 6; paragraph [0041], page 8; paragraph [0043], page 9; paragraph [0050], page 10; paragraph [0059], page 13; and paragraph [0088], pages 24-25. No new matter has been added.

Favorable consideration is respectfully requested in view of the following Amendments and Remarks.

II. Response to the Patent Office Assertion that the References Listed in the Specification Are Not in Proper Format for an Information Disclosure Statement

The Patent Office asserts that the references listed at pages 28-35 of the specification are not in proper format for an Information Disclosure Statement. Particularly, the Patent Office asserts that 37 C.F.R. §1.98(b) and MPEP §609.04(a) require that all information submitted for consideration by the Patent Office be submitted on a separate paper, and not merely listed in the specification.

In response, an Information Disclosure Statement is submitted herewith that addresses the references cited on pages 28-35 of the specification. Accordingly, applicants respectfully submit that this issue has been addressed.

III. Response to the Objection to Figure 4

The Patent Office has objected to Figure 4 as allegedly not corresponding to the brief description of Figure 4 in the specification. Particularly, the Patent Office asserts that Figure 4 shows 12 completely black boxes, and as such, does not indicate inhibition of angiogenesis in mice as asserted in the brief description of Figure 4.

In response, applicants respectfully submit that a color copy of Figure 4 was submitted at the time of filing the subject application, along with requisite petition to accept color drawings. Applicants further submit that the noted deficiencies in Figure 4 are due to the Patent Office's scanning procedures, and are not attributed to applicant error. Accordingly, as Appendix A, applicants have included herewith a copy of Figure 4 as originally filed, as a courtesy copy for the Examiner's use examining the subject application. Please note that the courtesy copy of Figure 4 is not intended as a replacement figure.

However, if (in view of the Patent Office's scanning procedures) the Examiner still requires replacement figures to be filed in the subject application, the Examiner is respectfully requested to contact the undersigned attorney and such replacement drawings will be filed.

IV. Response to the 35 U.S.C. § 102(b) Rejection of  
Claims 10-12 in view of Hicklin et al.

Claims 10-12 currently stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hicklin et al. Particularly, the Patent Office asserts that Hicklin et al. teaches antigen presenting cells that are dendritic cells, and an angiogenesis-related antigen that is VEGF, anticipating the presently claimed subject matter.

After careful review of the instant rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Preliminarily, applicants note that it is well settled that for a cited reference to qualify as prior art under 35 U.S.C. § 102, each element of the claimed invention must be disclosed within the reference. "It is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention." Hybritec, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986).

Without conceding to the assertions of the Patent Office, applicants respectfully submit that independent claim 10 has been amended herein to recite a composition for the treatment or prevention of cancer comprising: a) antigen presenting cells presenting at least one defined angiogenesis-related antigen; and b) antigen presenting cells presenting at least one tumor antigen. Support for the instant amendment to independent claim 10 can be found throughout the specification as filed, including particularly at paragraph [0020], page 5; paragraph [022], page 6; and paragraph [0059], page 13. No new matter has been added.

Applicants respectfully submit that Hicklin et al. do not disclose a composition comprising antigen presenting cells that present at least one defined angiogenesis antigen and antigen presenting cells that present at least one tumor antigen. Rather, the disclosure of Hicklin et al. appears to be limited to antigen presenting cells that present only an angiogenesis antigen, such as VEGF.

Independent claim 10 presently recites a composition for the treatment of cancer comprising antigen presenting cells presenting at least one defined angiogenesis-related

Serial No.: 10/613,262

antigen and antigen presenting cells presenting at least one tumor antigen. Accordingly, applicants respectfully submit that independent claim 10 has been patentably distinguished over Hicklin et al. Thus, the instant 35 U.S.C. §102(b) rejection of independent claim 10 is believed to be addressed.

Claims 11 and 12 depend from independent claim 10. Applicants respectfully submit that claims 11 and 12 have also been patentably distinguished over Hicklin et al., in view of their dependency from independent claim 10. Thus, the instant 35 U.S.C. §102(b) rejection of claims 11 and 12 is believed to be addressed.

Accordingly, applicants respectfully submit that the 35 U.S.C. §102(b) rejection of claims 10-12 has been addressed, and request that the instant rejection be withdrawn at this time. A Notice of Allowance is also respectfully requested.

V. Response to the 35 U.S.C. § 102(b) Rejection of Claims 10-15 in view of  
Nair et al. as Evidenced by Heer et al.

Claims 10-15 currently stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Nair et al., as evidenced by Heer et al. Particularly, the Patent Office asserts that Nair et al. teaches each and every element of the rejected claims, except the identification of mRNA encoding specific tumor antigens or other antigens present in poly A+ RNA prepared from breast cancer tumor cells. However, the Patent Office asserts that breast cancer tumor cells inherently comprise mRNA encoding the tumor antigen CEA and further comprise mRNA encoding for the angiogenesis related antigen VEGF, as evidenced by Heer et al. Thus, the Patent Office asserts that any preparation of poly A+ RNA prepared from a breast cancer tumor cell would comprise mRNA encoding both VEGF and CEA, and a cell prepared using total poly A+ RNA from a breast cancer cell, as taught by Nair et al.

After careful review of the instant rejection and the Patent Office's basis therefore, applicants respectfully traverse the rejection and submit the following remarks.

Serial No.: 10/613,262

Initially, applicants respectfully submit that Nair et al. appears to disclose antigen presenting cells transfected with unfractionated poly A+ RNA derived from tumors, such as breast cancer tumor. Applicants further submit that Heer et al. appear to disclose that breast cancer cells express mRNA encoding the angiogenesis antigen VEGF and the tumor antigen CEA. The Patent Office alleges that the polyA+ RNA from a breast cancer cell, as taught by Nair et al. would have inherently comprised mRNA encoding VEG and CEA. However, applicants respectfully submit that expression of VEGF is not necessarily inherent in all breast cancer tumors. For example, Heer et al. disclose that lobular carcinoma of the breast failed to reveal significant VEGF mRNA expression (See, Heer et al. page 3493, left column).

Further, independent claim 10 has been amended herein to recite a composition for the treatment of cancer comprising antigen presenting cells presenting at least one defined angiogenesis-related antigen and antigen presenting cells presenting at least one tumor antigen, as discussed in more detail herein above. Accordingly, claim 10 is believed to be distinguished over Nair et al. Particularly, applicants respectfully submit even if the breast cancer cells disclosed in Nair et al. expressed VEGF, Nair et al. does not teach or suggest a composition for the treatment of cancer comprising antigen presenting cells presenting at least one defined angiogenesis-related antigen and antigen presenting cells presenting at least one tumor antigen, such as can be provided by transfection of antigen presenting cells with a defined angiogenesis antigen in addition to tumor derived RNA.

Applicants further submit that the presently claimed composition for the treatment of cancer comprising antigen presenting cells presenting at least one defined angiogenesis-related antigen and antigen presenting cells presenting at least one tumor antigen provides synergistic results. For example, see Figure 6 of the subject application, which compares the combination of B16 tumor RNA and Tie2 angiogenesis factor RNA, or the combination of MBT-2 tumor RNA and VEGFR-2 angiogenesis RNA to individual RNAs combined with an actin control RNA. Thus, it is believed that any rejection of the present claims under 35 U.S.C. §103 would be improper.

Serial No.: 10/613,262

Applicants respectfully submit that independent claim 10 has been patentably distinguished over Nair et al. as evidenced by Heer et al. Accordingly, applicants respectfully submit that the instant 35 U.S.C. §102(b) rejection of independent claim 10 has been addressed.

Claims 11-15 depend from independent claim 10. Accordingly, applicants respectfully submit that claims 11-15 have also been patentably distinguished over Nair et al. as evidenced by Heer et al., in view of their dependency from independent claim 10. Thus, the instant 35 U.S.C. §102(b) rejection of claims 11-15 is believed to be addressed.

Additionally, claim 14 has been amended herein to recite the composition of claim 10, wherein the same antigen presenting cells present both said defined angiogenesis-related antigen(s) and said tumor antigen(s). Support for the amendment to claim 14 can be found throughout the specification as filed, including particularly at page 6, paragraph [0022]. No new matter has been added. Accordingly, in amended claim 14, the same antigen presenting cell presents both antigens. Applicants respectfully submit that this combination is not taught by Nair et al., or indeed by any of the cited art of record. Applicants further submit that Heer et al. does not make up for the deficiencies of Nair et al., or indeed of any of the cited art of record. Thus, the instant 35 U.S.C. §102(b) rejection of claim 14 is believed to be further addressed.

Accordingly, applicants respectfully submit that the 35 U.S.C. §102(b) rejection of claims 10-15 has been addressed, and request that the instant rejection be withdrawn at this time. A Notice of Allowance is also respectfully requested.

#### VI. Discussion of New Claims 19-35

New claims 19-35 have been added herein as indicated above. Support for new claims 19-35 can be found throughout the specification as filed, including particularly at paragraph [0018], page 5; paragraph [0019], page 5; paragraph [0022], page 6; paragraph [0041], page 8; paragraph [0043], page 9; paragraph [0050], page 10;

Serial No.: 10/613,262

paragraph [0059], page 13; and paragraph [0088], pages 24-25. No new matter has been added.

Applicants respectfully submit that new claims 19-35 are patentable over the references cited by the Patent Office for the reasons set forth herein above with respect to claims 10-15, and that new claims 19-35 are allowable over the cited art of record. Accordingly, allowance of these claims is respectfully requested.

#### VII. Conclusion

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and such action is earnestly solicited.

If any minor issues should remain outstanding after the Examiner has had an opportunity to study the Amendment and Remarks, it is respectfully requested that the Examiner telephone the undersigned attorney so that all such matters may be resolved and the application placed in condition for allowance without the necessity for another Action and/or Amendment.

Serial No.: 10/613,262

DEPOSIT ACCOUNT

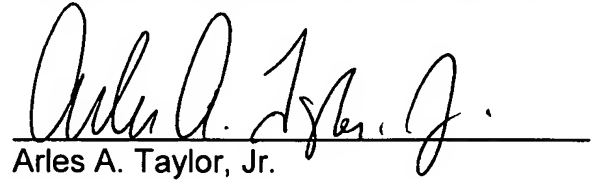
The Commissioner is hereby authorized to charge any additional fees associated with the filing of this correspondence, to Deposit Account No. 50-0426.

Respectfully submitted,

JENKINS, WILSON, TAYLOR, & HUNT, P.A.

Date: October 10, 2006

By:



Arles A. Taylor, Jr.  
Registration No. 39,395

AAT/PAD/omb

Customer No. 25297

1430/13